

PTO/PCT Rec'd

MAR 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/018,321

Filed: 12/12/2001

1st Inventor: SHIRAISHI, M.

For: Benzazepine Derivative, Production and Use

Atty. Dkt. No. 2614 US0P

Art Unit: tba

Examiner: tba

Allowed:

Batch:

Paper No.:

Response to Notice of Missing Parts

BOX Missing Parts
Commissioner for Patents
Washington, D.C. 20231
Sir:

In response to the Notice of Missing Parts mailed April 26, 2002, Applicants respectfully respond that this notice has been sent by mistake, as the Declaration was filed with the Application on 12/12/2001.

Applicants herewith submit a true and correct copy of the executed declaration of the inventors as originally filed. Also enclosed is a copy of the Transmittal letter, Certificate of Express Mailing, and Return Postcard, all listing the Declaration as filed with the Application on 12/12/2001. A copy of the incorrect Notice of Missing Parts is enclosed.

Withdrawal of the Notice of Missing Parts is requested.

Should the Examiner believe that a conference with applicants' attorney would advance prosecution of this application, the Examiner is respectfully invited to call applicants' attorney.

Respectfully submitted,

Dated: May 3, 2002

(847)383-3372

(847)383-3391

Mark Chao, Ph.D., Reg. No. 37,293

Elaine M. Ramesh, Ph.D., Reg. No. 43032

Attorney for Applicants

Customer No. 23115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

Application No.:	tba	Art Unit:	tba
Filed:	tba	Examiner:	tba
1 st Inventor:	Mitsuru SHIRAISHI	Allowed:	
For:	Benzazepine Derivative, Production and Use Thereof	Batch:	
Atty. Dkt. No.	2614 USOP	Paper No.:	1



CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL No. EL 916492262 US

DATE IN: December 12, 2001

Itemized Papers/Items:

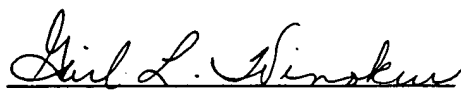
1. This Postcard (1 page) and Certificate of Express Mailing (2 pages)
2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
3. Copy of Request form of the International Application PCT/JP00/03879, (Form PCT/RO/101)(5 pages)
4. English Translation of the International Application as filed in Japanese [This includes Specification total 550 pages, including Claims 1-37 (9 pages), Abstract (1 page)] and transmittal (1 page)
5. Preliminary Amendment (15 pages)
6. Information Disclosure Statement (1 page) with Form PTO-1449 (1 page), and copies of references (3)
7. Copy of Forms PCT/IB/301, 304, 308 and 332 (4 pages)
8. Copy of the front page of the International Application as published (WO 00/76993) (1 page)
9. Declaration and Power of Attorney (5 pages)
10. Assignment (2 pages) and Assignment Recordation cover Sheet (1 page X 2)
11. Copy of International Search Report (2 pages)

The undersigned hereby certifies that the above itemized papers are together being deposited with the Express Mail Post Office to Addressee service of the United States Postal Service (USPS) in an envelope with sufficient postage, having the USPS Express Mail Label No. shown above, and addressed to:

BOX PCT
Commissioner for Patents
Washington, D.C. 20231.

on this date, 12/12/01

Dated: 12/12/01


Gail L. Winokur

EL916492262US

COPY

EC14 Rec'd PCT/PTO 12 DEC 2001

Application No.:	tba	Art Unit:	tba
Filed:	tba	Examiner:	tba
1 st Inventor:	Mitsuru SHIRAKASHI	Allowed:	
For:	Benzazepine Derivative, Production and Use Thereof	Batch:	
Atty Dkt. No.	2614 USPTO	Paper No.:	1

The USPTO is requested to kindly acknowledge receipt of the following items:

1. This Postcard (1 page) and Certificate of Express Mailing (2 pages)
2. Transmittal Letter for Filing under 35 USC 371 (2 pages X 2)
3. Copy of Request form of the International Application PCT/JP00/03879, (Form PCT/RO/101) (5 pages)
4. English Translation of the International Application as filed in Japanese [This includes Specification total 550 pages, including Claims 1-37 (9 pages), Abstract (1 page)] and Transmittal (1 page)
5. Preliminary Amendment (15 pages)
6. Information Disclosure Statement (1 page) with Form PTO-1449 (1 page), and copies of references (3)
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8. Copy of the front page of the International Application as published (WO 00/76993) (1 page)
9. Declaration and Power of Attorney (5 pages)
10. Assignment (2 pages) and Assignment Recordation cover Sheet (1 page X 2)
11. Copy of International Search Report (2 pages)

Respectfully submitted 12/12/01 For Customer No. 23,115
Express Mail Label No. EL 916492262 US
By Elaine M. Ramesh, PhD, JD - Reg. No. 43,032

10/018321



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ORIGIN (POSTAL USE ONLY)

PC ZIP Code 50067	Day of Delivery First <input checked="" type="checkbox"/> Second <input type="checkbox"/>	Flat Rate Envelope <input type="checkbox"/>
Date In 12/12/01	Time 12 Noon <input type="checkbox"/> 3 PM <input type="checkbox"/>	Postage \$
Time In 6:45 AM <input checked="" type="checkbox"/> PM <input type="checkbox"/>	Int'l Alpha Country Code	Return Receipt Fee
Weight 3 lbs. 3 ozs.	Acceptance Clerk Initials	COD Fee
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday <input type="checkbox"/>	Total Postage & Fees \$ 39.85	Insurance Fee

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PHONE 843 383-3372

MARK CHAO
TAKEDA PHARMACEUTICALS
NORTH AMERICA INC
475 HALF DAY RD STE 500
LINCOLNSHIRE IL 60069-2935

Docket #2614 USOP

TO: (PLEASE PRINT)

PHONE ()

BOX PATENT APPLICATION PCT
COMMISSIONER OF
PATENTS & TRADEMARKS
WASHINGTON DC 20231-0001

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UNITED STATES
POSTAL SERVICE

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Wkstn sys5003	Cashier	KSVZX5
Cashier's Name	Min	
Stock Unit Id	MINSSA	
PO Phone Number	847-634-3260	

1. Exp. Mail PO-ADD	0.00
Destination:	20231
Weight:	12lb 2.40oz
Postage Type:	None
Total Cost:	39.85
Base Rate:	39.85
Label#:	EL916492262US
Corporate Acct.:	600672
Amount Charged:	39.85

Subtotal	0.00
Total	0.00

Number of Items Sold: 1

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UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20210
www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/018,321	FIRST NAMED APPLICANT Mitsuru Shiraishi	ATTY. DOCKET NO. 2614 USOP
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INTERNATIONAL APPLICATION NO. PCT/JP00/03879

I.A. FILING DATE 06/15/2000	PRIORITY DATE 06/16/1999
--------------------------------	-----------------------------

CONFIRMATION NO. 2839

371 FORMALITIES LETTER



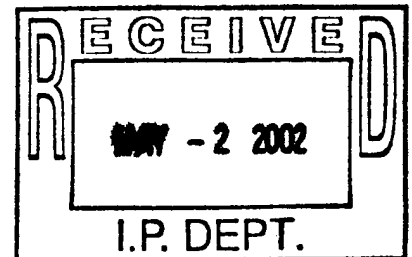
23115
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

Date Mailed: 04/26/2002

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Priority Document
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Information Disclosure Statements
- Preliminary Amendments
- Request for Immediate Examination



The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- \$130 Surcharge for providing the oath or declaration later than the appropriate 30 months from the priority date (37 CFR 1.492(e)) is required.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

SHELBY J VIGIL

Telephone: (703) 305-3653

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/018,321	PCT/JP00/03879	2614 USOP

FORM PCT/DO/EO/905 (371 Formalities Notice)



PTO/PCT Rec'd 7 MAR 2002

Please type a plus sign (+) inside this box → ☐

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/018,321	
	Filing Date	12/12/2001	
	First Named Inventor	SHIRAISHI, M.	
	Group Art Unit	tba	
	Examiner Name	tba	
Total Number of Pages in This Submission	16	Attorney Docket Number	2614 USOP

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input checked="" type="checkbox"/> Response to Missing Parts/ Incomplete Application <input checked="" type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Postcard. Certificate of Express Mailing Copy of Executed Declaration Copy of Express Mail certificate Copy of Certificate of Express Mailing Copy of Notice to File Missing Parts
Remarks		The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account 500799.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Mark Chao, Ph.D., JD, Reg. No. 37,293
Signature	
Date	5/7/02

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class ^{EXPRESS} mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: 5/7/02			
Typed or printed name	Gail L. Winokur	Date	5/7/02
Signature		Date	5/7/02

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Express Mail # EV 0826 75041 US

2614 USOP

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371INTERNATIONAL APPLICATION NO.
PCT/JP00/03879INTERNATIONAL FILING DATE
June 15, 2000PRIORITY DATE CLAIMED
June 16, 1999

TITLE OF INVENTION

Benzazepin D rivative, Production and Us Th r of

APPLICANT(S) FOR DO/EO/US

Mitsuru SHIRAIISHI, Masanori BABA, Yoshio ARAMAKI, Naoyuki KANZAKI, Osamu NISHIMURA

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:

Copy of ISR and copies of Cited References

Copies of Forms 210 (ISR), 301, 304, 308, 332, and PCT/RO/101

Translation Cover Sheet, Copy of Front Page of International Appln., Itemized Return Postcard

Express Mail Label No. EL 916492262 US

Date of Deposit 12/12/01

21. ☒ The following fees are submitted:**BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):**

Neither international preliminary examination fee (37 CFR 1.482)
nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO
and International Search Report not prepared by the EPO or JPO \$1040.00

International preliminary examination fee (37 CFR 1.482) not paid to
USPTO but International Search Report prepared by the EPO or JPO \$890.00

International preliminary examination fee (37 CFR 1.482) not paid to USPTO
but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00

International preliminary examination fee (37 CFR 1.482) paid to USPTO
and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00

ENTER APPROPRIATE BASIC FEE AMOUNT =**CALCULATIONS PTO USE ONLY**

\$ 890.00

Surcharge of \$130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS *	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	37 - 20 =	17	x \$18.00
Independent claims	3 - 3 =	0	x \$84.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$280.00

\$

\$

\$

\$

TOTAL OF ABOVE CALCULATIONS =

\$ 1,196.00

☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above
are reduced by 1/2.

\$

+

SUBTOTAL =

\$ 1,196.00

Processing fee of \$130.00 for furnishing the English translation later than ☐ 20 ☐ 30
months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE =

\$ 1,196.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be
accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +

\$

TOTAL FEES ENCLOSED =

\$ 1,196.00

***After entry of Preliminary Amendment**Amount to be
refunded:

\$

charged:

\$

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 500799 in the amount of \$ 1,196.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
overpayment to Deposit Account No. 500799. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card
information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Elaine M. Ramesh, PhD, JD
Takeda Pharmaceuticals North America, Inc.
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA
(847)383-3372 fax (847)383-3481

Elaine M Ramesh

SIGNATURE

Elaine M. Ramesh, PhD, JD

NAME

43,032

REGISTRATION NUMBER

For Customer No. 23,115



JG14 Rec'd PCT/PTO 07 MAY 2002

#7

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/018,321
Filed: 12/12/2001
1st Inventor: SHIRAISHI, M.
For: Benzazepine Derivative, Production and Use
Atty. Dkt. No. 2614 USOP

Art Unit: tba
Examiner: tba
Allowed:
Batch:
Paper No.:

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR 1.10

USPS EXPRESS MAIL LABEL. No. EV 082675041 US

DATE IN: May 7, 2002

Itemized Papers/Items:

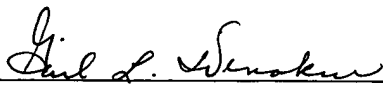
1. This Postcard and Certificate of Express Mailing (2 pages)
2. Transmittal Form (1 page X 2)
3. Copy of Executed Declaration previously filed on 12/12/2001 (5 pages)
4. Copy of date-stamped return postcard showing date of 12/12/2001 (1 page)
5. Copy of Express Mail Receipt showing the date in of 12/12/2001 (1 page)
6. Copy of Transmittal Letter dated 12/12/2001 (1 page)
7. Copy of Certificate of Express Mailing dated 12/12/2001 (1 page)
8. Response to Notice to File Missing Parts (1 page) and copy of Notice to File Missing Parts (2 pages)

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BOX MISSING PARTS
Commissioner for Patents
Washington, D.C. 20231.

on this date, May 7, 2002

Dated: 5/7/02


Gail L. Winokur

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA